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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,418	09/05/2003	David J. Parins	1001.1675101	7562

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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
04/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,418	PARINS, DAVID J.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *3-5,12-14,21,22,30,31,38,39 and 44-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-11,15-20,23-29,32-37 and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/16/2009 has been entered.

Notice of Amendment

2. In response to the amendment filed on 03/16/2009, amended claim(s) 1, 10, 19, 28, and 36 is/are acknowledged. The current rejections of the claim(s) 1, 6-11, 15-20, 23-29, 32-37, and 40-43 is/are *withdrawn*. The following new and/or reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 10, 15, 16, 17, 19, 23, 24, 25, 27, 28, 32, 33, 34, 36, 40, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Johansen et al. (US 7,303,533 B2, hereinafter Johansen).

5. For claims 10, 19, 28, and 36, Johansen discloses and shows an intracorporeal device (10 and/or 20) comprising a guidewire (10 and/or 20), comprising *inter alia*:

- an elongate shaft (column 2 lines 48-52) inherently having a proximal end and inherently having an opposing distal end;
- a helically wound coil (20) (as best seen in Figure 2) (column 3 lines 27-67) having a plurality of windings (24) (as best seen in Figure 2) (column 3 lines 27-67), inherently having an outer perimeter (the outer perimeter of helically wound coil 20 as best seen in Figure 2), and inherently forming a coil length (the coil length of helically wound coil 20 as best seen in Figure 2), said coil length disposed about a portion of the distal end of the elongate shaft (column 2 lines 48-52); and
- a plurality of joining elements (22) (as best seen in Figure 2) (column 3 lines 27-67) disposed on only a portion of the outer perimeter (as best seen in Figure 2) (as best seen in Figure 2) (column 3 lines 27-67) and along the coil length (as best seen in Figure 2) (column 3 lines 27-67), wherein each joining element only couples two or more coil windings (column 3 lines 27-67), and wherein each joining element is a discrete element (as best seen in Figure 2) (column 3 lines 27-67),
- wherein at least one of the at least ten joining elements is longitudinally offset from at least one other joining element in both the longitudinal and radial directions (as best seen in Figure 2) (the Examiner notes in Figure 2, each of the 3 welds are

offset radially from one another and additionally the welds 22 are offset from each other along an axial direction), and

- wherein at least one of the plurality of joining elements is longitudinally spaced apart from at least one other joining element with no longitudinal overlap in a direction along the longitudinal axis (as best seen in Figure 2) (the Examiner notes when looking down the coil along axis 26 the joining elements are spaced without overlap).

6. For claims 15, 23, 32, and 40, Johansen discloses and shows the guidewire, wherein the joining elements form a uniform pattern of joining elements along the coil length (as best seen in Figure 2) (column 3 lines 27-67).

7. For claims 16, 24, 33, and 41, Johansen discloses and shows the guidewire, wherein each joining element couples 3 to 10 coil windings (as best seen in Figure 2) (column 3 lines 27-67).

8. For claims 17, 25, 34, and 42, Johansen discloses and shows the guidewire, wherein each joining element is a discrete element aligned orthogonal to the windings in a radial direction (as best seen in Figure 2) (column 3 lines 27-67).

9. For claim 27, Johansen discloses and shows the guidewire, wherein each joining element is disposed on less than 1/10 of the outer perimeter of each winding (as best seen in Figure 2).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 6-9, 11, 18, 20, 26, 29, 35, 37, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen.

12. For claims 1, 6-9, 11, 18, 20, 26, 29, 35, 37, and 43 Johansen discloses and shows the guidewire as set forth and cited above, including the claim limitations of claims 6-8 (see paragraphs 6-8 above), except for expressly disclosing (a) the plurality of joining elements comprising at least ten joining elements disposed along the coil length and (b) each joining element has a width in the range of 0.1 to 0.5 mm and a length in the range of 0.1 to 1.5 mm.

13. As evidenced by Applicant "the number and size of the joining elements can be varied to obtain the desired characteristics". The Specification at at least pages 7-8 reads as follows:

14. "A plurality of joining elements 120 can be disposed along the coil length L. The joining elements couple a plurality of coil windings 105 together. Each joining element 105 may join from 2, 3, 4, 5, 6, 7, 8, 9, or 10 or more coil windings 105 together. There may be 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40 or more joining elements 120 disposed in a uniform or non-uniform pattern along the coil length. In at least some embodiments, the joining elements 120 may only function to join coil windings 105 together. For example, in at least some embodiments, the coil joining element or elements 120 join a plurality of coil windings 105 together, but do not act to join any other structure within the device 100. In such embodiments, the coil

joining element or elements 120 act only to join coil windings 105 together, and do not join any other structure to the coil. For example, in some such embodiments, the joining elements 120 do not join the coil 110 to the shaft or core 130.

15. "The joining elements 120, by interconnecting a series of coil windings, can provide enhanced torque transmission along the coil length L and/or enhanced push-ability while still providing flexibility that a coil 110 offers. The degree of enhanced torque transmission and/or push-ability is dependent at least in part on the number of joining elements along the length of the coil, and the size of each joining element (i.e. the number of coil windings joined be each joining element). Those of skill in the art, and others will recognize that as a general proposition, that greater enhanced torque transmission and/or push-ability can be achieved by using a greater the number of joining elements along a coil length, and/or by increasing the number of coil windings 105 joined by each joining element 120. The number and size of the joining elements 120 can be varied to obtain the desired characteristics.

16. "In some embodiments, the joining elements 120 may have a length in the range of about 0.1 to about 1.5 mm and a width in the range of about 0.1 to about 0.5 ram. The joining elements 120 can be discrete elements aligned orthogonal to the coil windings 105 as illustrated in Fig. 1. The joining elements 120 may be formed of a material the same as or different from the coil 110. The coil windings 105 define an outer perimeter 150. The joining elements 120 can be disposed about the outer perimeter 150 such that only a portion of the outer perimeter 150 is covered by joining

elements 120. In some embodiments, each joining element 120 may be disposed on less than 1/l0 of the total outer perimeter 150 of each winding 105."

17. Johansen discloses the claimed invention but does not disclose expressly the number and size of the joining elements as claimed. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the guidewire as taught by Johansen with the number and size of the joining elements as claimed, because Applicant has not disclosed that the number and size of the joining elements as claimed provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with configuration of the joining elements as taught by Johansen, because it provides for configuring the degree of stiffness, flexibility, and torqueability of the guidewire by altering the number of welds (i.e. joining elements) (column 3 lines 55-58) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Johansen. Therefore, it would have been an obvious matter of design choice to modify Johansen to obtain the invention as specified in the claim(s).

Response to Arguments

18. Applicant's arguments, see pages 11-13 filed 03/16/2009, have been fully considered but they are not persuasive.

19. Applicant argues Johansen does not disclose, teach, and/or fairly suggest a medical device, wherein *inter alia*:

- (a) at least one of the at least ten joining elements is longitudinally offset from at least one other joining element; and/or
- (b) at least one of the plurality of joining elements is longitudinally spaced apart from at least one other joining element with no longitudinal overlap.

20. Applicant in support of (a) and (b) further argues

- "nowhere do Johansen et al. appear to teach that welds 22 may be disposed axially along the length of the coil, offset or spaced apart from one another in a longitudinal direction" and
- "Johansen et al. do not appear to disclose welds 22 offset or spaced axially along the coil length".

21. The Examiner disagrees, reiterates the rejection as set forth and citied above, and in response notes the following:

22. Johansen discloses and shows the medical device, wherein at least one of the at least ten joining elements is longitudinally offset from at least one other joining element in both the longitudinal and radial directions (as best seen in Figure 2) (the Examiner notes in Figure 2, each of the 3 welds are offset radially from one another and additionally the welds 22 are offset from each other along an axial direction), and wherein at least one of the plurality of joining elements is longitudinally spaced apart from at least one other joining element with no longitudinal overlap in a direction along the longitudinal axis (as best seen in Figure 2) (the Examiner notes when looking down the coil along axis 26 the joining elements are spaced without overlap).

23. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "welds 22 may be disposed axially along the length of the coil") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

24. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "welds 22 offset or spaced axially along the coil length") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736